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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/603,387 | 06/25/2003 | Noel P. Bouck | 053662-5018-04 | 4772 |
| 28977 | 7590 | 10/04/2005 | EXAMINER | |
| MORGAN, LEWIS & BOCKIUS LLP 1701 MARKET STREET PHILADELPHIA, PA 19103-2921 | | | QIAN, CELINE X | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1636 | |

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------------------------------|-------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/603,387 | BOUCK ET AL. |
| | Examiner Celine X. Qian Ph.D. | Art Unit 1636 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 31,32,43 and 44 is/are pending in the application.
 - 4a) Of the above claim(s) 31 and 32 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 43 and 44 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 June 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>0603</u> . | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____. |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

DETAILED ACTION

Claims 31, 32, 43 and 44 are pending in the application.

Election/Restrictions

Applicant's election without traverse of Group II in the reply filed on 8/8/05 is acknowledged.

Accordingly, claims 31 and 32 are withdrawn from consideration for being directed to non-elected subject matter. Claims 43 and 44 are currently under examination.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 43 and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,670,333 B2 and claims 1 and 2 of US 6,288,024. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed invention of claims 43 and 44 is obvious in view of the disclosure of US 6,670,333.

Claims 43 and 44 are drawn to a method of inhibiting neovascularization in an eye by transfecting endothelial cells associated with the eyes with a vector comprising an isolated

nucleic acid encoding PEDF, or transfecting said vector into a population of other cells, wherein the PEDF is secreted from said other cells and contacting said PEDF with endothelial cells, wherein such contact result in inhibition of neovascularization.

Claims 1-6 if the US 6,670,333 is drawn to a method of inhibiting angiogenesis within a tissue by transfecting endothelial cells associated with said tissue with a vector comprising an isolated nucleic acid encoding SLED/PEDF or fragment thereof, or transfecting said vector into a population of other cells, wherein the PEDF is secreted from said other cells and contacting said PEDF with endothelial cells, wherein such contact result in inhibition of neovascularization.

Although the claims do not specify inhibiting angiogenesis within an eye, the specification discloses in one of the embodiments wherein said method is applied to inhibition of angiogenesis in an eye tissue, in which case the presence of exogenous PEDF will inhibit novel angiogenesis associated with a variety of disorders of the eye (see col.4, 3rd paragraph). Therefore, it would have been obvious claims 1-6 of US 6,670,333 encompass the invention of claims 43 and 44 of the instant application.

Claims 1 and 2 of US 6,288,024 are drawn to a method of inhibiting angiogenesis within an eye tissue by providing exogenous SLED/PEDF to endothelial cells associated with said tissue under conditions sufficient for PEDF to inhibit angiogenesis. Although the claims do not reciting providing exogenous PEDF in the form of nucleic acid, the specification discloses that PEDF polypeptide can be provided to the tissue of interest by transferring an expression vector comprising a nucleic acid encoding PEDF. Therefore, it would have been obvious that the instantly claimed invention of claim 43 and 44 is obvious in view of the teaching of US 6,288,024.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
Art Unit 1636

**CELIAN QIAN
PATENT EXAMINER**

